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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,694	04/09/2004	William Alejandro Thompson	P25130	8732

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EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1611	

NOTIFICATION DATE	DELIVERY MODE
01/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/820,694	THOMPSON, WILLIAM ALEJANDRO	
	Examiner	Art Unit	
	Isis A. Ghali	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-7 and 13-25* is/are pending in the application.

4a) Of the above claim(s) *1-17, 20, 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt is acknowledged of applicant's amendment filed 09/26/2008.

Claims 1-20 previously presented. Claims 8-12 have been canceled, and claims 21-25 have been added.

Claims 1-7, 13-25 are pending.

Election/Restrictions

1. Newly submitted claim 25 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly added claim 25 is directed to method that is distinct from the method of claim 18. Claim 25 is directed to method of treating symptoms resulting from transdermal delivery of an active agent, while claim 18 is directed to treating pain, ache or inflammation that can be caused by arthritis or skin inflammation and not necessary caused by another active agent. The method of claim 25 is applied on different group of population that is receiving a transdermal active agent that causes symptoms.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for

prosecution on the merits. Accordingly, claim 25 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. This application contains claims 1-7, 13-17, 20, 25 drawn to an invention nonelected with traverse in the reply filed on 12/19/2007. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 18, 19, 21-24 are included in the prosecution.

The following rejections have been overcome by virtue of applicant's amendment and remarks:

(A) The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by US 5,527,832 (832).

(B) The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by US 5,780,047 ('047).

(C) The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by US 5,976,566 ('566).

(D) The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by US 6,083,996 ('996).

(E) The rejection of claim 18 under 35 U.S.C. 102(b) as being anticipated by US 2001/0036489 ('489).

The following new grounds of rejections are necessitated by applicants' amendment:

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 18, 19, 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 as amended recites "first" and "second". In accordance to MPEP 714.02, applicant should specifically point out to where in the disclosure a support for any amendment made to the claims can be found.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "standard sized bathtub" in claim 24 is a relative term which renders the claim indefinite. The term "standard sized bathtub" is not defined by the claim, the specification does not provide a standard for ascertaining the

requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 18, 19, 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US '5,780,047 ('047), US 5,342,535 ('535), US 2001/0036489 ('489) and US 6,083,996 ('996).

US '047 teaches patch applied to the skin to provide topical excellent effects of reliving pain and stiffness (abstract; col.2, lines 14-25; col.11, lines 34-38). The patch comprises active ingredient including anti-inflammatory agents and permeation enhancer including myristic acid (col.6, line 61; col.7, lines 39-52; col.8, lines 15-16; col.10, line 34). The patch further comprises sodium bicarbonate and citric acid (col. 7, lines 10-15). The reference teaches that the patch can be poured or dissolved in bathwater followed by bathing (col.11, lines 12-14), and it is expected that when the patch comprising sodium bicarbonate is poured or dissolved in water will form effervescent because compounds and their properties are inseparable. The patch

disclosed by the reference reads on table since it comprises the ingredients of the claimed tablet and used for the same purpose as desired by applicant.

Although US '047 teaches the elements of claim 19, however, the reference does not teach the amount of different ingredients as claimed by claim 19. US '047 does not explicitly teach the patch as tablet. Although US '047 teaches anti-inflammatory agent in the disclosed patch and myristic acid, however, does not explicitly teach ibuprofen and isopropyl myristate.

US '535 teaches effervescent tablet formulated to include active agent such as analgesic soaks to provide therapeutic effect in contact with the user skin (col.3, lines 36-43; col.4, lines 61-68). The effervescent bath tablet comprises 36.99% by weight sodium bicarbonate, 37.15% by weight citric acid (example 2 at col.5).

US '489 teaches treating rheumatoid arthritis and osteo-arthritis using bathing composition comprising anti-inflammatory agent including ibuprofen for at least once a day (paragraphs 0094-0101; 0140). The composition may comprise sodium bicarbonate and citric acid (paragraph 0126).

US '996 teaches topical formulation for NSAID delivery for management of pain comprising the drug and permeation enhancer including isopropyl myristate (abstract; col.1, lines 10-14; col.2, lines 1-5; col.4, lines 1-60; col.6, lines 47-49, examples). Example 27 at col.17 shows the composition comprising 5% ibuprofen and 5% isopropyl myristate.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide product that can be poured or dissolved in bathwater

to relive pain and stiffness and comprises anti-inflammatory agents, permeation enhancer, sodium bicarbonate and citric acid as disclosed by US '047, and deliver the ingredients in an effervescent tablet comprises specific amounts of sodium bicarbonate and citric acid as disclosed by US '535 because US '535 teaches that such effervescent tablet is formulated as analgesic soaks to provide therapeutic effect in contact with the user skin, and further add ibuprofen to the effervescent tablet forming the analgesic soak as disclosed by US '489 because US '489 disclosed that arthritis pain can be treated by ibuprofen included in the bathwater, and further one having ordinary skill in the art would adjust the amount of the ibuprofen to form 5% by weight of the tablet and replace the myristic acid with 5% isopropyl myristate because US '996 teaches such combination and amounts are preferred for topical delivery and pain management, with reasonable expectation of having effervescent tablet comprising 5% ibuprofen, 5% isopropyl myristate, 36.99% by weight sodium bicarbonate, 37.15% by weight citric acid that treat pain from different causes effectively when applied in bathwater.

Response to Arguments

9. Applicant's arguments filed 09/26/2008 have been fully considered but they are not persuasive.

Applicant traverse this rejection by arguing that the office action failed to show a reason why one of ordinary skill in the art would combine US '047 with any of the secondary references to cure the deficiency of US '047.

In response to this argument, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide product that can be poured or dissolved in bathwater to relive pain and stiffness and comprises anti-inflammatory agents, permeation enhancer, sodium bicarbonate and citric acid as disclosed by US '047, and deliver the ingredients in an effervescent tablet comprises specific amounts of sodium bicarbonate and citric acid as disclosed by US '535 because US '535 teaches that such effervescent tablet is formulated as analgesic soaks to provide therapeutic effect in contact with the user skin, and further add ibuprofen to the effervescent tablet forming the analgesic soak as disclosed by US '489 because US '489 disclosed that arthritis pain can be treated by ibuprofen included in the bathwater, and further one having ordinary skill in the art would adjust the amount of the ibuprofen to form 5% by weight of the tablet and replace the myristic acid with 5% isopropyl myristate because US '996 teaches such combination and amounts are preferred for topical delivery and pain management, with reasonable expectation of having effervescent tablet comprising 5% ibuprofen, 5% isopropyl myristate, 36.99% by weight sodium bicarbonate, 37.15% by weight citric acid that treat pain from different causes effectively when applied in bathwater. Therefore,

there is motivation to combine US '047 with all the secondary references, and the invention as a whole is taught by the combination of the cited prior art.

Applicant argues that US '047 teaches a method wherein a composition in form of a patch is preferably first administered to a patient before the patient takes a bath. Applicant notes that it would be counterintuitive to one of ordinary skill in the art to apply the teachings of US '047 and reverse the order of application by first dissolving the composition in a bath prior to administering to a body part. Applicant further argues that a physiological effect would be minimized by diluting any dosage form in a bath before a body part comes in contact with the active ingredient.

In response to this argument, it has been held that it is *prima facie* obvious to reverse the order of the prior art process steps, *Ex parte Rubin* , 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). Applicants failed to show superior and unexpected results obtained from first dissolving the ingredients and second immersing the body part. Additionally, the terms "first" and "second" are interpreted by examiner as numbering the steps in terms of number of the steps and not in terms of order of performance. Regarding applicant's argument that the physiological effect would be minimized by diluting the dosage form from the bath, it is argued that the cited prior art recognized inclusion of the composition comprising active agent in water of bath, and the combination of the references teaches composition for

dissolving in water bath comprising the same ingredients in the claimed amounts, and therefore expected to have the same effect upon dissolving in water bath. Therefore, the concentrations of the ingredients of the composition disclosed by the combination of the prior art is calculated with consideration of their dilution in water of the bath.

Applicant argues that US '535 discloses an effervescent formulation. Even assuming that the above combination is proper, one of ordinary skill would not be motivated to dissolve a composition first in a bath and then immerse the body part in the bath. This deficiency is not cured by US '996 as this document refers to "an aqueous pharmaceutical composition of semi-solid consistency". As for US '489, Applicant argues that the combination of US '047 and US '489 would still not teach or suggest to one of ordinary skill in the art to first dissolve a pharmaceutical composition in a bath prior to immersing a body part therein.

In response to this argument, it has been held that it is *prima facie* obvious to reverse the order of the prior art process steps, *Ex parte Rubin* , 128 USPQ 440 (Bd. App. 1959). See also *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946), selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results; *In re Gibson*, 39 F.2d 975, 5 USPQ 230 (CCPA 1930). Applicants failed to show superior and unexpected results obtained from first dissolving the ingredients and second immersing the body part. Additionally, the terms "first" and "second" are interpreted by examiner as numbering the steps in terms of number of the steps and not in terms of order of performance. The claims' language does not exclude

semisolid composition disclosed by US '535. US '535 is relied upon for the solely teaching of effervescent tablet that is formulated as analgesic soaks to provide therapeutic effect in contact with the user skin, and US '489 is relied upon for the solely teaching of effervescent ibuprofen tablet forming the analgesic soak. US '996 is relied upon for the solely teaching of the amount of the ibuprofen and isopropyl myristate.

It has been held that "When a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR Int 'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. AG Pro, Inc.,* 425 U.S. 273,282 (1976)). "When the question is whether a patent claiming the combination of elements of prior art is obvious," the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." In addition, "To determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit. But it need not seek out precise teachings directed to the challenged claim's specific subject matter, for a court can consider the inferences and creative steps a person of ordinary skill in the art would employ". Pp. 11-14. KSR INTERNATIONAL CO. v. TELEFLEXINC. ET AL. (2007).

It is well established that the claims are given the broadest interpretation during examination. A conclusion of obviousness under 35 U.S.C. 103 (a) does not require absolute predictability, only a reasonable expectation of success; and references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosure. *In re Bozek*, 163 USPQ 545 (CCPA 1969).

In the light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been prima facie obvious within the meaning of 35 U.S.C. 103 (a).

Applicant argues that the sole dispersing and/or dissolution of an active ingredient such as ibuprofen in bath water does not result in the requisite absorption of the active ingredient through the skin to obtain the beneficial effect. Rather, an oil phase including a skin permeation enhancer layer has to present to adsorb evenly across the skin and enhances permeation of the active ingredient across the skin barrier. Thus, the oily layer across the skin is essential to ensure desired permeation of the active ingredient. Furthermore, absorption into the skin even continues after the body or body part is removed from the bath because the oily layer across the skin still contains active ingredients that permeate the skin.

In response to this argument, it is argued that all the steps of the present method and all the elements of the claimed composition are taught by the combination of the prior art. The diffusion of the composition resulting from the combination of the cited prior art through the skin is expected to be the same as the present composition since

compounds and their properties are inseparable, and since the structure of the skin is the same for every mammalian species.

Claim Objections

10. Claim 25 is objected to because of the following informalities: the claim is missing a period at the end of the claim. Appropriate correction is required.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571) 272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IG

/Isis A Ghali/
Primary Examiner, Art Unit 1611